

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/085,051	SITAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dr. Kailash C. Srivastava	1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to March 30, 2004.
2. ☒ The allowed claim(s) is/are 17-26.
3. ☒ The drawings filed on 01 March 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date <u>03/30/2004</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>06/07/2004</u> .</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### EXAMINER'S AMENDMENT

1. Applicants' responsive amendment and remarks filed March 30, 2004 in response to Office Action mailed October 1, 2003 is acknowledged and entered.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Mark Nuell on June 07, 2004.

In the Claims:

Cancel Claims 1-2, 4-10 and 12-16 and replace them with the following claims:

--

17. A method for detecting spermine/spermidine N<sup>1</sup>-acetyltransferase (SSAT) activity in a mammal comprising the steps of:
  - a) incubating an amount of amantadine in a mammal;
  - b) obtaining a tissue or cell or body fluid sample from the mammal; and
  - c) detecting acetylamantadine in the sample; and
  - d) correlating the presence of acetylamantadine to SSAT activity, wherein the presence of the acetylamantadine in the sample is indicative of SSAT activity in the mammal.

18. A method as in Claim 17, wherein the amount of amantadine is equivalent to 1-4 mg/kg.
19. A method as in Claim 17, wherein the sample is a blood or urine sample.
20. A method as in Claim 17, wherein the urine sample is collected 2-24 hours post-incubating said amantadine in the mammal.
21. A method as in Claim 17, wherein the urine sample is collected 8 hours post-incubating said amantadine in the mammal.
22. A method as in Claim 17, wherein the step of correlating the amount of acetylamantadine in the sample comprises correlating to a standard curve to determine the level of SSAT activity in the mammal.
23. A method as in Claim 17, wherein the acetylamantadine level is detected by gas chromatography.
24. A method for assaying SSAT activity in a mammal comprising the steps of:
  - a) contacting a test sample obtained from the mammal with amantadine;
  - b) measuring the amount of acetylamantadine produced; and
  - c) relating the amount of acetylamantadine produced to a level of SSAT activity by comparison to a standard curve.
25. The method of Claim 24, wherein the sample is a homogenate of a liver tissue and the contacting step is performed at a pH of about 7.8.

26. The method of Claim 26, wherein step a) comprises incubating the sample with the substrate for about 10 minutes at 37°C.

--

3. The following is Examiner's statement of reasons for allowance:

The specification is only enabled for amantadine as non-spermine/non-spermidine substrate for SSAT, because the specification explicitly demonstrates that only acetylamantadine was detected with amantadine as a substrate for SSAT and that transgenic male mice over expressing SSAT had a level of SSAT activity in the liver that is 4 fold higher with amantadine as substrate than that observed in non-transgenic mouse (See Specification, Page 12, Lines 4-6). Furthermore, mouse liver preparations as SSAT source did not show spermidine acetylation (See Specification, Page 11, Line 17).

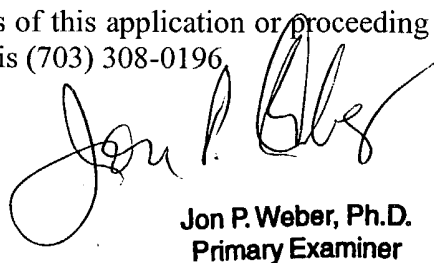
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(571) 272-0923  
June 07, 2004

  
Jon P. Weber, Ph.D.  
Primary Examiner